compliance with postoperative surveillance. It is possible that some events not captured here could have altered the statistical conclusions. As 10 patients had both limbs enrolled in this cohort, nonindependence of the patient and at least some of the anatomic characteristics could have affected the statistical conclusions. The total implant length variable was chosen to encapsulate both disease severity and intraoperative decision making, which differs from length of the treated segment. Due to a lack of uniform use of angiographic distance markers in this series, lesion length was not available for analysis.

CONCLUSIONS

Reintervention rates following Viabahn treatment for FPOD were >40% within the first year, and more than half of the observed clinical events were MALE. TASC D lesions, small-diameter (5 mm) devices, number and summed length of devices implanted, and distal collateral coverage are adverse factors to be carefully considered in patient selection and intraoperative decision making. Our results suggest particular caution in the treatment of claudicants who have multiple unfavorable anatomic characteristics for stent grafts as outlined herein. The importance of dual-antiplatelet therapy after Viabahn graft placement seems paramount. Further studies are needed to clarify the clinical effectiveness of covered stents in the treatment of FPOD; however, our results provide insights to guide the application of this technology until higher-quality data are available.

AUTHOR CONTRIBUTIONS

Conception and design: PJ, SV, CO, MC
Analysis and interpretation: PJ, SV, CO, MC
Data collection: PJ, SV, SR
Writing the article: PJ, MC
Critical revision of the article: PJ, SV, SR, JH, CE, CO, DS, MC
Final approval of the article: PJ, SV, SR, JH, CE, CO, DS, MC
Statistical analysis: PJ, CO, MC
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Overall responsibility: PJ

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DISCUSSION

Dr Gregory L. Moneta (*Portland Ore*). This study is retrospective, so we expect some data to be missing. Some deficiencies are expected and, to the author's credit, acknowledged. However, there are some very basic data missing. We really don't know how the patients were selected for placement of these covered stent grafts. There is no pre- and posttreatment hemodynamic information. Follow-up is best described as inconsistent and the authors could not provide quantitative information on patency; although by implication, patency was poor. There is no information on quality of life. There is no cost information with respect to the initial procedure. We don't know if wounds healed or walking improved. The data do not allow us to be convinced the patients

were not candidates for more traditional treatments, such as a good old fashioned vein bypass! Overall, we get the impression the procedures were performed without careful ongoing assessment of results similar to those cardiologists and interventional radiologists we were all so critical of 15 years ago. As they say, "we have looked at the enemy and he is us!" On a more serious note, in my opinion, evaluation of a new procedure in one's practice requires a heightened level of vigilance that seems to be lacking here.

What has this study confirmed? It confirms Willard Johnson's data from, I believe, the early 90s, that smaller-caliber prosthetic grafts for treatment of femoral popliteal occlusive disease do not do well. Category: "Wheel: reinvention of"! It certainly confirms my bias that prosthetic devices of any sort for infrainguinal occlusive disease remain suboptimal and best avoided if possible. The study does confirm these devices can be reliably placed with a high technical success rate, although one would have to ask with the data presented, why you would want to?

We have confirmed that the Rutherford classification of limb ischemia needs to be seriously reassessed. No so-called critically ischemic limb in this series ended up with an amputation despite all the graft failures. Perhaps these were not necessarily all that critically ischemic limbs? Finally, we have basically confirmed there is no free lunch in vascular surgery. Even in the endovascular era, failure still comes with a price and a really good small-caliber arterial substitute remains the Holy Grail of vascular surgery.

However, we have learned a few things; some good, some bad. We have learned, with a little effort, we can apparently change the natural history of the limb in patients with claudication to be similar to that of the natural history of the limb in patients with critical limb ischemia. That is not a good thing. We have learned engineers continue to be smarter than biochemists. Engineers can design clever devices, but the biochemists still have not figured out how to stop the intimal hyperplasia induced by these clever devices. Endovascular therapy for infrainguinal occlusive disease is going to get better. Despite all the marketing, however, real improvement will not occur until the biochemists catch up with the engineers.

What is good? The paper is well written. The author's observations on implant length/number and diameter, on coverage of collateral vessels and the potential utility of dual-antiplatelet therapy are of real importance and should be taken seriously by anyone wishing to implant these devices. The analysis of the data that is available is honest and first rate.

I have a few questions:

1. Is there still enthusiasm for this procedure at UCSF?
2. There are some longer term risks with dual-antiplatelet therapy. What proportion of peripheral arterial disease patients can tolerate aspirin and clopidogrel long term? Have you any suggestion as to when to stop dual-antiplatelet therapy, if ever?
3. Would you use a good arm vein over this stent graft in a patient with critical limb ischemia?
4. Follow-up is a problem for anyone doing clinical research, especially retrospective clinical research. What are you doing to improve follow-up in your patients? Dr Johnston now works at Kaiser in Denver. I look to Kaiser to help us with preventative medicine. Do you do anything different at Kaiser with respect to patient follow-up than was done at UCSF?

Dr Paul C. Johnston. Dr Moneta, thank you for your honest and critical appraisal.

1. I would have to confirm that, yes, enthusiasm for this procedure has waned at UCSF. After we started seeing some of these patients come back with acute limb ischemia, red flags started going up, and that was the impetus for starting this project. Once the data were collected and analyzed, it further changed our perspective.
2. This is an unanswered question. Although we have anecdotally not seen major bleeding complications with dual-antiplatelet therapy, this study was not designed to capture all bleeding events that may have occurred outside of our direct care. There is no clear time point based on our data when the appropriate time point to stop dual-antiplatelet therapy may be. As a result, we have kept patients on both agents unless a contraindication arises.
3. Therapy has to be individually tailored. In a patient with a reasonable life expectancy and the ability to tolerate a potentially lengthy procedure under general anesthesia, arm vein is a good option.
4. At Kaiser, we do benefit from a more closed system than exists at many university hospitals such as UCSF. The electronic medical record and finite set of care providers facilitates ongoing follow-up both in terms of in-person office visits and surveillance studies. We are also taking coordinated steps toward establishing surveillance protocols and patient registries for all permanent implants. There is an unmet need to establish registry databases that we can all use to better track patient outcomes.